Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
09651		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/008471	10.06.2004	10.06.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant		
Dainippon Sumitomo Pharma Co., Ltd.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/008471

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-29 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. 2-11,15-23,25 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1,12,13,14,24 received by this Authority on 08.04.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets fig. 1-4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/008471

Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 22,23

because:

☒ the said international application, or the said claims Nos. 22,23
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions that are set forth in claims 22 and 23 are commercial methods and advertisement methods, and as such correspond to methods for carrying out business activities. Thus, claims 22 and 23 relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Rule 67.1(iii).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 22,23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/008471

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-11, 24, 25	YES
	Claims	12-21	NO
Inventive step (IS)	Claims	1-11	YES
	Claims	12-21, 24, 25	NO
Industrial applicability (IA)	Claims	1-21, 24-25	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: CHEST, Vol. 123, No. 5, May 2003, pp. 1375 to 1378

Claims 12 to 21, 24 and 25

Document 1 presents a method wherein D-dimer specific monoclonal antibodies are employed in order to measure the level of D-dimers in a patient who presents with an acute aortic dissection.

The reagents that are set forth in claims 12 to 21 can be considered to include antibodies that are capable of recognizing the appropriate D-dimers for identifying the illnesses that are set forth in said claims. However, as substances, the D-dimer specific monoclonal antibodies that are presented in document 1 are the same as the antibodies that are set forth in claims 12 to 21, and said D-dimer specific monoclonal antibodies can be considered to have a configuration that is suitable for identifying the illnesses that are set forth in claims 12 to 21.

Therefore, the inventions that are set forth in claims 12 to 21 lack novelty (refer to section 5.23 of the PCT International Search and Preliminary Examination Guidelines).

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

In addition, it would have been natural for a person skilled in the art to employ antibodies in order to configure reagents.

Claims 1 to 11

The feature of measuring the level of D-dimers in the blood of a patient who presents with either an acute aortic dissection or an acute myocardial infarction and then determining that said patient may have suffered an acute aortic dissection in cases when the measured D-dimer concentration exceeds a pre-set cut-off value for the level of D-dimers in the blood, and the feature of measuring the level of the D-dimers in the blood and then determining whether or not a Stanford A-type acute aortic dissection, a Stanford B-type acute aortic dissection or an acute myocardial infarction has occurred based on the concentration of the D-dimers in the blood are not disclosed in any of the documents that are cited in the international search report, and would not have been obvious to a person skilled in the art.